



UK IN A CHANGING EUROPE

UK-EU REGULATORY
DIVERGENCE TRACKER

INTRODUCTION

Freedom from Brussels's regulatory orbit and the power to do things differently was a central argument for Brexit among many eurosceptics. And as we approach a year since the signing of the Trade and Cooperation Agreement, the government – and Lord Frost in particular – are starting to talk more about what this 'British renaissance' might look like. So where has the government exercised its newfound regulatory freedom? Or where indeed has it decided not to keep pace with changes in the EU? And what are the consequences of these decisions?

This is the first edition of UK in a Changing Europe's UK-EU regulatory divergence tracker, which compiles the most significant cases of divergence in regulatory standards between the UK and EU. The tracker is not an exhaustive summary of all changes but rather aims to identify and analyse the most notable cases. It was originally submitted to the House of Lords European Affairs Committee in September 2021, in order to aid the Committee's wider functions. This version has been updated to cover changes up to the start of October 2021.

Given the tracker covers changes since the end of the transition period, it is likely more extensive than future editions, reporting 19 cases of what we have identified as significant divergence. We have defined those as being changes that lead to clear and tangible differences compared to if the UK were still in the EU. We distinguish between what we label 'passive' and 'active' divergence. The former occurs when the UK simply does not keep up with changes on the EU side. Active divergence, by contrast, occurs when the UK – or some part of it – deliberately legislates to move away from retained EU law.

In terms of passive divergence, the EU has new proposals on the regulation of carbon emissions, chemicals, medical devices and copyright protections which would outstrip UK standards. There are outstanding questions as to whether the UK is simply happy to fall behind EU standards in these areas, or would rather keep pace but has not yet done so (which in turn invites further questions about whether it presently lacks the resources to keep up).

In cases of active divergence, the UK has mostly sought to decrease rather than increase regulation, compared to EU standards (although there are exceptions such as on the export of live animals and the regulation of online harms). Proposals around GDPR, fintech, state aid, gene editing and environmental regulation all demonstrate new UK regulatory plans which are designed to reduce the administrative burden on some or all affected businesses, and are often accompanied by explicit statements from the government about aims to increase trade or innovation as a result. Some are also subject to consultation as part of the Taskforce on Innovation, Growth and Regulatory Reform's (TIGRR) proposals for areas to reform. We will continue to report on these initiatives as they take clearer shape over time.

Finally, there are cases where the UK and EU have not diverged in terms of standards, but where the UK has needed to establish its own regulatory body and/or system. Examples of such 'procedural divergence' include the establishment of the new UKCA product mark to replace the EU's CE marking, and new regimes to regulate chemicals, medicines and SPS goods. Procedural divergence often implies an additional set of regulations for businesses to comply with despite UK and EU standards being similar or identical (consider the replacement of passporting rights for financial services with equivalence regimes), resulting in increased bureaucracy and potentially risking the supply of certain goods or services to either the UK or EU market, if businesses are forced to prioritise one regime over another.

Cases are grouped and ordered by the lead department relating to the issue in question (BEIS, DCMS, Defra, DfT, DHSC, HMT). We have presumed not to cover cases of divergence (such as the end of free movement between Britain and EU, and the loss of financial passporting rights) which were settled as soon as the transition period ended. In many cases divergence does not impact the whole of the UK in the same way, either because the competency is devolved, or because Northern Ireland remains aligned to EU standards on certain issues. We have made clear where this is the case and elaborated on the implications for each part of the UK.

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ISSUE	SOURCE & STATUS	IMPLICATIONS & IMPACT	TIMELINE & REGION
<p>1. CLIMATE AND ENVIRONMENT</p> <p>PASSIVE</p> <p><i>EU introduces 'Carbon Border Adjustment Mechanism', which imposes a carbon tariff on imports of certain goods</i></p>	<p>The EU has published proposals for a new <u>Carbon Border Adjustment Mechanism</u> (CBAM). Imports of iron and steel, cement, aluminium, electricity and some fertilisers will be taxed with a tariff equivalent to what EU producers pay on their carbon emissions under the <u>EU's Emissions Trading Scheme</u> (ETS).</p> <p>The CBAM is designed to protect against carbon leakage, whereby producers of certain goods move their operations outside of the EU in order to avoid the higher carbon prices imposed by the EU ETS. The CBAM effectively ensures that third country producers pay the same prices as EU producers.</p>	<p>The EU is the UK's main export market for many of the goods subject to the CBAM. <u>Very provisional estimates</u> (made before the CBAM plans were published) suggested the cost of CBAM tariffs on UK business could be up to €1bn. However, as UK ETS prices are currently similar to the EU's, importers of UK products may be able to avoid most or all CBAM tariffs if they can prove their goods have already paid the necessary 'carbon price' in the UK market. However, additional administrative costs are <u>unavoidable</u>: for instance registering with a national authority, calculating emissions, and purchasing certificates. Equally, should the UK ETS carbon price fall relative to the EU's, significant CBAM tariffs may be incurred.</p> <p>The UK could avoid those implications if it chose to integrate its ETS with the EU's, as Switzerland <u>has done</u>. There is as yet <u>no indication</u> that the UK wishes to do this, even though such a possibility is included in the Trade and Cooperation Agreement (TCA).</p>	<p>CBAM regulations are subject to approval in the coming months, following discussions at European Parliament and member state level. If approved, the CBAM will <u>begin in 2026</u>, although a reporting system (to facilitate the rollout) will be phased in from 2023.</p> <p>There is the potential for new product types to be</p>

		<p>There are also implications for the Northern Ireland Protocol. The UK and EU must decide whether the CBAM regulation falls within the Protocol’s scope. The EU is likely to argue it should, as NI is currently part of the UK ETS for everything except electricity (where it is part of the EU ETS). For the EU, this creates a risk that carbon-intensive goods from GB or NI could pass into the single market – via the Irish border - without completing the necessary paperwork (or potentially paying the correct tariff). Checks on goods between NI and Ireland would undermine the Protocol’s purpose. An alternative is to extend ‘not at risk’ classification to CBAM goods entering NI, but this would not resolve the problem of goods produced in NI being able to cross the Irish border without paying the CBAM tariff.</p>	<p>added to the CBAM in future.</p>
<p>2. CLIMATE AND ENVIRONMENT</p> <p>PASSIVE</p> <p><i>EU widens scope of and sets more ambitious targets for its Emissions Trading Scheme</i></p>	<p>In July 2021 the EU published proposals to alter the terms of its emissions trading scheme (ETS), in order to meet an increased ambition of a 55% reduction in carbon emissions by 2030.</p> <p>If adopted, these changes would widen the scope of the EU ETS to include maritime emissions (from vessels over 5,000 tonnes, covering 100% of intra-EU journeys, 50% of those entering or leaving an EU port, and 100% of emissions from</p>	<p>The proposals widen the scope of the EU ETS beyond what is covered by the UK ETS (launched in May 2021), making it harder for UK and EU ETS schemes to be aligned in future, unless the UK decided to change its scheme too.</p> <p>As discussed in entry #1, greater divergence in standards between UK and EU ETS schemes increases the likelihood of UK exports being subject to EU CBAM tariffs in future.</p>	<p>The new ETS for road transport and the heating of buildings will be operational from 2026.</p> <p>The EU’s proposals are subject to</p>

	<p>vessels berthed at an EU port). They would increase the speed at which emissions are reduced from 2.2% to 4.2% per year.</p> <p>Finally, another separate ETS will be introduced to cover road transport and the heating of buildings from 2026.</p>		<p>scrutiny and approval from the European Parliament and member states over many months.</p>
<p>3. CLIMATE AND ENVIRONMENT</p> <p>PROCEDURAL</p> <p><i>UK no longer permitted to label products with EU's 'CE' mark to demonstrate compliance with standards; introduces own 'UKCA' mark</i></p>	<p>Following the end of the transition period, the EU <u>stopped recognising</u> the competency of UK bodies to assess manufactured goods for the EU market, and to issue the 'CE' product marking which demonstrates goods are compliant with EU standards. As a result, in January 2021 the UK introduced a new '<u>UKCA</u>' marking, issued by UK 'Approved Bodies', which demonstrates that goods (and the processes used to complete them) are compliant with UK standards.</p> <p>The UK was set to keep recognising the CE marking until the end of 2021, but in August 2021 the deadline was extended to the end of 2022, following serious concerns about businesses readiness (see next column). The UKCA marking is not recognised in the EU.</p> <p>For the time being, the UKCA marking applies to most goods covered by the CE marking, as well as aerosol products, and the technical requirements which products must meet are</p>	<p>The extension of the deadline for the end of CE recognition in the UK reflects the struggles of businesses to prepare for the change. UKCA status requires approval by UK-based Approved Bodies, which were <u>facing a significant backlog</u> due to the scale of demand for approvals (in some cases needing to complete <u>64 years' worth of testing in seven months</u>). A range of trade groups have warned that the UK does not have sufficient capacity to handle demand, and that many EU suppliers were not ready to obtain a UKCA mark – risking gaps in UK supply chains. In cases where EU businesses supply only a small number of goods or components to the UK, many are also not willing to take on the costs of getting these certified by a UK body. This risks EU-produced component goods vital to the manufacturing processes of GB businesses going absent from the GB market.</p>	<p>UKCA marks apply to GB but not NI, which will continue to observe CE marks under the terms of the NI Protocol. Deadline for end of UK recognition of CE mark has been pushed back to the end of 2022.</p>

	<p>largely the same as under the CE marking. This could change if UK and EU regulations diverge in product-specific areas.</p> <p>In Northern Ireland, the CE marking will continue to be recognised alongside a new ‘UKNI’ marking for products assessed in GB for placement on the NI market. GB-assessed goods placed on the NI market <u>must carry</u> both the UKNI and CE marks. BEIS <u>has guaranteed</u> that, for NI businesses, goods recognised in NI will be allowed to be placed on the GB market (i.e. with only a CE marking).</p>	<p>Although the deadline has been pushed back, the challenge remains of how to ensure EU suppliers which are vital to GB supply chains apply for the necessary UKCA mark before 2023. One solution would be for the UK to accept CE marked goods in perpetuity.</p> <p>In addition, once the CE mark stops being recognised in 2023, there will be <u>new costs</u> for GB businesses with complex supply chains where component goods cross between GB and EU during manufacturing (such as the automotive sector). These components will need to obtain duplicate UKCA and CE marks demonstrating compliance in both markets: doubling the approval needed despite standards being highly aligned. Should UK and EU standards diverge, they will also need to conform to two separate sets of rules, adding further complication. Likewise, goods produced in GB to be sold into NI will also need to carry both the UKNI and CE markings. This risks goods shortages in NI if some suppliers are not aware of the dual demands, or do not bother to apply for an additional CE marking.</p>	
<p>4. COMPETITION POLICY</p> <p>PROCEDURAL</p>	<p>UK and EU competition regulations (the prohibition of anti-competitive agreements and abuse of dominance) were substantively aligned at the end of the transition period. UK</p>	<p>The significant convergence in competition rules internationally makes it unlikely either the UK or EU will take a drastically different approach in the foreseeable future.</p>	<p>These changes affect all of the UK and they took</p>

<p><i>UK establishes own architecture for regulation of competition law</i></p>	<p>law followed precedents set by the Court of Justice of the European Union (CJEU) and was applied in parallel to EU law where necessary. The substance of UK and EU competition regulations remains the same for the time being.</p> <p>Nevertheless, the UK is now an independent competition law jurisdiction, no longer required to follow precedents of the CJEU, with the Competition and Markets Authority (CMA) and UK courts not required to apply EU competition law alongside UK law. It is notable that unlike most other areas of regulation, they can even depart from pre-Brexit precedent, where there is very good reason to do so.</p> <p>This means that both regulatory systems now apply in parallel to each other, in relation to businesses which operate and trade in both the UK and the EU, and could diverge. Under the terms of the TCA, both jurisdictions are required to maintain and enforce competition rules, but the TCA does not prescribe how those rules should be designed or applied.</p>	<p>Neither side is likely to seek to undercut the other through weaker regulation, as this will ultimately harm their own markets and consumers.</p> <p>Yet over time there is significant scope for diverging approaches to how business behaviour with ambiguous competitive effects will be treated. The UK and EU authorities may have diverging interpretations of what is in their consumers’ interests. Indeed, the UK is already forging its own approach to competition in big tech markets, <u>introducing a watchdog</u> called the Digital Markets Unit under the CMA, to oversee a new ‘pro-competition’ regime (consultation on the regime’s design ongoing).</p> <p>Other drivers of divergence include the question of whether competing businesses should be allowed to exchange commercially sensitive information to help facilitate sustainability and the green economy, and the use of ‘national security’ and ‘public interest’ type policy considerations to block or force through a merger or acquisition.</p> <p>The most significant immediate effect of divergence is the administrative cost of compliance for businesses operating in the UK and EU. They must now navigate two regulatory</p>	<p>effect on 1 January 2021. Further major changes are unlikely to occur, as Brexit has resulted in the scaling up of UK competition regulation that previously only applied to smaller UK competition law infringements and proposed mergers. The key focus will be on how the CMA, Competition Appeal Tribunal and the High Court choose to interpret post-Brexit points of law relating to competition regulation.</p>
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<p>5. STATE AID</p> <p>ACTIVE</p> <p><i>UK introduces own rules and infrastructure for the regulation of state subsidies</i></p>	<p>The <u>Subsidy Control Bill</u> was introduced to Parliament on 30 June 2021. The UK stopped following EU state aid rules – which prohibit government financial assistance to businesses which would distort trade – following the end of the transition period.</p> <p>As per TCA requirements, the Bill adopts a regulatory regime that applies a similar set of principles to the EU’s, with clear provisions for dispute resolution including retaliatory measures. One additional, UK-specific, principle is that</p>	<p>BEIS’s stated aim was to create a subsidy control system that was less bureaucratic and more flexible, reflected in the system relying on challenges before the courts, rather than prior approval. While removing some bureaucracy, it <u>could see</u> a weakening in regulation, with some harmful subsidies potentially going unchallenged if there is no party willing to take the decision to court. How this plays out is uncertain and could depend on how prevalently subsidies are used</p>	<p>The Bill has just completed second reading in the Commons. The new UK regime is therefore not yet in place and subject to change.</p>

	<p>subsidies must be designed in a way that limits negative effects on competition and investment within the UK.</p> <p>However the TCA gave the UK <u>freedom over how to design its system</u>, and it has opted for greater flexibility than the EU's. Unlike under the EU system, where authorities have to seek prior approval for subsidies before they grant them, the UK system allows them to self-assess subsidies against established principles, and seek advice where necessary from a new Subsidy Advice Unit (SAU), sitting with the Competition and Markets Authority (CMA). Subsidies 'of particular interest' will be mandatorily referred to the SAU, but it is as yet <u>unclear</u> how this will be defined.</p> <p>Companies will have to go via the UK court system if they seek arbitration in cases where they think the government has provided unfair support to a competitor.</p>	<p>going forward to pursue wider government goals such as levelling up and net zero.</p> <p>The Institute for Government also <u>expressed concerns</u> that too light-touch an approach could lead to inconsistent decisions and the allowance of poorly-designed subsidies. Inconsistent decisions could have a 'chilling' effect, if authorities are uncertain around what is permissible and thus become reluctant to hand out subsidies out of fear of legal challenge. Yet the organisation <u>finds</u> the system announced by the government to be coherent, and notes that the advisory role which the CMA will have to play in most 'high-profile' cases means there should be a high degree of legal confidence.</p> <p>There are also consequences for the devolved nations. The UK regime prevents a public authority in one region using public money to cause a business to move jobs there from another region. This may limit the freedom of devolved administrations (including some English cities) to make targeted spending decisions to pursue local policy objectives. This has led to the Welsh government <u>expressing concern</u> about possible "reverse devolution", with the Bill</p>	
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		<p>removing previously available tools to direct support towards the poorest regions.</p> <p>Under Article 10 of the Northern Ireland Protocol, EU state aid rules continue to apply to goods that are traded between NI and the EU. This could very quickly escalate into a full-blown political crisis, as UK state aid decisions which impact NI need referring to Brussels for approval. In July 2021, the government <u>argued that</u> the publication of the Subsidy Control Bill made the existing provisions of Article 10 redundant, because it, combined with existing commitments to shared principles in the TCA, “provide a more than sufficient basis to guarantee that there will be no significant distortion to goods trade between the UK and EU”. A September 2021 legal paper by George Peretz QC and James Webber <u>argued</u> that these proposals should be “considered seriously”.</p> <p>UK businesses also have less protection than before in one important respect: challenges to unlawful subsidy decisions by the EU from UK businesses may need to be made by the HMG through the dispute provisions of the TCA, where previously they would have made a complaint directly to the European Commission.</p>	
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6. DIGITAL AND DATA

PASSIVE

EU imposes greater obligations on internet companies to identify and remove copyright violations in user-uploaded content

The UK chose not to adopt – as part of EU exit legislation - the terms of the 2019 EU Directive on Copyright in the Digital Single Market: a framework of more stringent internet-related copyright regulations. Member states had until June 2021 to introduce new laws to reflect its provisions.

Article 17 of the Directive imposes greater obligations on internet companies which host user-generated content (e.g. YouTube, Facebook, TikTok) to identify and remove copyrighted content. It demands that companies 1) make ‘best efforts’ to get licences for copyrighted material appearing on their site (even if posted by a user), 2) remove all forms of any specific work identified by rightsholders on their site and 3) block future uploads of content that has been previously removed. This means tech companies will have to develop policies and algorithms for content filtering, as well as identifying rightsholders and pursuing licenses where necessary. There are exemptions where copyrighted material may be used – for example in parody and quotation.

As it has not adopted the new Directive, UK rules relating to tech companies hosting copyrighted material remained underpinned by ‘safe harbour’ provisions – themselves

By not adopting the new EU Directive, the UK has diverged from the EU’s copyright standards in relation to user-generated content, with less significant obligations on internet companies to identify and address copyright infringements.

For large tech companies, life is likely to be easier in the UK where the ‘safe harbour’ provisions place fewer obligations on them. A Commons DCMS Committee report suggests this allows such companies to uphold their dominance: for example, a company such as YouTube gains an ongoing competitive advantage against smaller music streaming platforms because its users repeatedly upload music – rights free – onto the site, with little obligation on YouTube to remove it. As a result, when YouTube comes to negotiate the rights to stream artists’ music on its platform, it typically pays less than competitors as users are already providing the content on its site.

The UK could seek to impose its own regulations to supersede the safe harbour rules, but it has so far not done so. Tech companies will argue that the regulations undermine the free expression of internet users, with rightsholders overusing the process and companies taking down non-infringing content. These companies may also

EU member states were obliged to introduce new laws by June 2021. We can expect further EU regulation on big tech in future, but it is unclear if the UK will pursue greater regulation on copyright protection around user-generated content.

	<p>transposed from previous EU law. Under safe harbour, tech companies avoid liability for copyrighted material hosted on their platform if they do not ‘have actual knowledge of unlawful activity or information’, and the imposition of general monitoring obligations on companies is prohibited. This contrasts with the EU’s new demand that companies make ‘best efforts’ to identify infringements.</p>	<p>find the lacuna in UK law around copyright protection – similar to US standards – attractive, which could make the UK a preferred location long-term. On the other hand it means rightsholders in the UK are afforded fewer protections against said companies.</p> <p>With the more activist approach which the EU is taking to big tech regulation – as part of its plan for ‘digital sovereignty’ – it is likely that more divergence will occur by default in future years as the EU bolsters its regulations vis-à-vis the dominance of the biggest companies. The Commons DCMS Committee <u>takes the view that</u> “the Government must provide protections for rightsholders that are at least as robust as those provided in other jurisdictions.”</p>	
<p>7. DIGITAL AND DATA</p> <p>ACTIVE</p> <p><i>UK plans new rules around data protection with aim to reduce</i></p>	<p>The government is seeking to diverge from elements of the EU’s General Data Protection Regulation (GDPR), replacing it with a more ‘light touch’ framework with less ‘box ticking’. The EU <u>calls</u> its GDPR rules “the toughest privacy and security law in the world”, imposing significant obligations on individuals around the protection of data they collect on people.</p>	<p>The EU has <u>warned</u> that it will intervene “<u>if the UK deviates from the level of protection currently in place</u>”, most likely by removing its adequacy agreement. It is also worth noting that the inclusion of a 2025 sunset clause in the UK adequacy decision is unprecedented for the EU, and it has <u>said</u> it will renew the agreement in 2025 “only if the UK continues to ensure an adequate level of data protection”.</p>	<p>The EU’s data adequacy decision for the UK lasts until 2025.</p> <p>DCMS launched a consultation in September 2021 as the first step</p>

<p>obligations for many</p>	<p>For the time being the UK <u>remains fully compliant</u> with the principles of EU’s GDPR and Law Enforcement Directive, which govern its data privacy rules. The EU adopted a decision recognising the adequacy of the UK regime in June 2021, meaning there is a free flow of personal data between the UK and EU until 2025, when the <u>decision expires</u> under a ‘sunset clause’.</p> <p>However, in February 2021, then-DCMS Secretary of State Oliver Dowden <u>outlined a vision</u> in which the UK maintains “world-class standards” on privacy, but does not “copy and paste” the EU’s GDPR rule book “word-for-word”. In August 2021, he <u>elaborated</u> on what this will entail: reduced obligations for small charities and businesses to limit the bureaucracy they have to navigate; cutting the use of cookie banners on websites; and relaxing marketing requirements to make it easier for (e.g.) churches to advertise events in parish newsletters. The government will also seek to strike new data partnerships with non-EU countries (USA, Australia, Colombia, Singapore, South Korea and Dubai have been prioritised).</p> <p>DCMS launched a <u>public consultation</u> in September 2021 which it describes as “the first step in the process of</p>	<p>The consequences of losing the EU adequacy agreement would be significant. EY’s director of trade strategy <u>estimates</u> that it would cost a large corporation millions of pounds a year, as businesses operating in the UK and EU would have to comply with a dual set of regimes and additional bureaucracy. The UK could elect to continue to recognise the EU’s GDPR standards in this scenario, which would mean no extra obstacles for UK-based companies requesting data transfers from the EU.</p> <p>There is a potential ‘data dividend’ for the UK if it can develop a less onerous system where – for instance – smaller businesses need not meet the full standards of GDPR. Oliver Dowden <u>argued</u> that innovation is presently hampered because “too many businesses and organisations are reluctant to use data — either because they don’t understand the rules, or are afraid of inadvertently breaking them.”</p> <p>The UK also believes that its own data regime would be more “agile” than the EU’s and therefore find it easier to strike data adequacy agreements with other countries, encouraging global trade. The EU has only declared 12 regimes adequate in the past few decades, and the government estimates that barriers caused by data transfers</p>	<p>towards reform of personal data protection.</p>
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	<p>reforming the UK’s regime for the protection of personal data.” Responses are due by 19 November.</p>	<p>have cost the UK £11bn in unrealised service exports. This could be backed up by <u>additional funding</u> for the sector governed by the UK’s own state aid regime. The UK must consider how far it is willing to risk losing EU adequacy for such dividends.</p> <p>Finally, changes to cookies regulation <u>could enable</u> greater data harvesting and profiling of individuals by online corporations.</p>	
<p>8. DIGITAL AND DATA</p> <p>ACTIVE</p> <p><i>UK and EU each set out plans for new rules on how to regulate harmful behaviours online</i></p>	<p>The UK and EU are both taking forward plans for the regulation of online harms. The overarching aim is to police harmful behaviours which take place on the internet, whilst maintaining rights to freedom of expression online.</p> <p>In December 2020 the UK published its <u>Online Harms White Paper</u> (which has now evolved into the <u>Draft Online Safety Bill</u>) and the EU published its <u>Digital Services Act</u>. They share an emphasis on shifting from <u>liability to responsibility</u> when it comes to the behaviour of internet platforms. However, there are differences in approach.</p> <p>The new EU rules <u>ramp up</u> the obligations on internet platforms, covering transparency, decision-making functions, codes of conduct and crisis response controls,</p>	<p>The UK approach is <u>seen to impose</u> more onerous obligations upon internet platforms – who must comply with an existing legal concept in ‘duty of care’, whereas EU regulations impose specific obligations with a relatively wide range of exceptions. This is a notable case of the UK imposing tougher restrictions on internet platforms than the EU (contrasting with divergence around copyright and GDPR – see entries #6 and #7). For example, under the Bill Ofcom <u>has reserved powers</u> to pursue criminal action against named senior managers who do not comply with its requests for information.</p> <p>There are <u>some questions</u> about whether large internet platforms will, in practice, be able to implement all of the UK demands. The other <u>main concerns</u> around the Bill appear to</p>	<p>A Joint Committee of both Houses has been established to consider the government’s draft legislation. The Committee must report by 10 December 2021.</p> <p>The EU’s proposals are presently being discussed at Parliamentary and Member State</p>

	<p>with the level of obligation increasing for larger organisations.</p> <p>The UK approach focuses on <u>imposing a ‘duty of care’</u> upon platforms to prevent the proliferation of illegal content and activity online, and applies to providers all over the world who have users in the UK. This duty of care is a more all-encompassing concept, compared to the defined set of obligations imposed by the EU rules. The UK imposition of a duty of care was made possible by Brexit, as it <u>no longer has to follow</u> the EU’s E-Commerce Directive.</p>	<p>centre on issues of freedom of speech (and its regulation being outsourced to tech companies), rather than about the consequences of divergence from EU standards. However there is the potential that the dual regimes will mean tech companies have to ensure compliance with <u>two sets of standards</u>. Which regime is prioritised by companies <u>may depend</u> on whether others such as the US choose to follow the EU or UK model in their own future harms legislation.</p>	<p>level, so are subject to change. The adoption of new rules is expected in 2022.</p>
<p>9. ANIMAL WELFARE</p> <p>ALIGNMENT</p> <p><i>UK accepts EU ruling permitting animal testing for certain cosmetic products</i></p>	<p>The European Chemicals Agency (ECHA – an EU regulatory body) last year ruled that the German chemicals company Symise would have to carry out animal testing on two specific ingredients - used only in cosmetics - to ensure their safety.</p> <p>This decision runs up against laws in place in both the UK (since 1998) and EU (since 2013) which ban the use of animal testing on ingredients used solely for cosmetics. However, in practice such animal testing has continued to take place on products for the UK and EU markets since their respective bans. The ECHA requires animal testing on around 150 ingredients used in cosmetic products as a ‘last</p>	<p>The Home Office’s decision has surprised many, as it has made an active decision to align itself with EU rules, foregoing the opportunity to impose higher animal welfare standards – and encourage greater use of scientific innovation which also promotes sustainability – post-Brexit.</p> <p>Industry experts point to non-animal tests, known as ‘new approach methodologies’ (NAMs), as an alternative strategy which the UK could have pursued. They view these methods as more sustainable and cutting-edge, compared to animal testing which is based on 30+ years old technology and is also less human species-relevant. Dr Julia Fentam, head of Unilever’s safety and environmental assurance centre, <u>called</u></p>	<p>UK decision to conform to ECHA standards was reported in August 2021, based on a letter from the Home Office seen by the Guardian.</p> <p>The letter reportedly said HMG would publish updated policy and</p>

	<p>resort' where other tests aren't available. The Symise decision is <u>not the first of its kind</u>, but it has received notably more publicity than other cases.</p> <p>The Symise case also marks a notable development in the UK's post-Brexit policy. In August 2021, the Guardian <u>reported</u> that the Home Office would be aligning itself with the ECHA's decision. This is a new and explicit recognition, post-Brexit, by the government of the potential need to test cosmetic ingredients on animals, that was never made when the UK was an EU member.</p>	<p>the decision to remain aligned to the ECHA's standards rather than pursue greater use of NAMs a "retrograde step".</p> <p>CFI's director of science and regulatory affairs, Dr Katy Taylor, <u>said</u>: "This decision blows a hole in the UK's longstanding leadership of no animal testing for cosmetics" (UK legislation was finalised 15 years before the EU's and set modern standards) "and makes a mockery of the country's quest to be at the cutting edge of research and innovation."</p> <p>A factor in the UK's decision could be that regulators tend to prefer traditional animal testing, since few understand the new science and how to apply it for safety decisions. This may thus be a case of UK ambition being ahead of industry practice. The EU <u>expects</u> that by 2027, the vast majority of additional data tests on products (which is where the exemptions to the animal testing ban arise) will be done via NAMs.</p>	<p>guidance having in due course.</p>
<p>10. ANIMAL WELFARE</p> <p>ACTIVE</p> <p><i>New law to ban the export of live</i></p>	<p>The Animal Welfare (Sentience) Bill is at report stage in the House of Lords. Its <u>overarching purpose</u> is to recognise animals as sentient beings in English and Welsh law – something that was lost with the exit from the EU. However, the government is also seeking to improve animal welfare</p>	<p>The banning of live animal exports will mean diverging standards within the UK. The National Farmers' Union (NFU) <u>has argued</u> that English and Welsh producers will be discriminated against (and perhaps suffer competitive disadvantage) as their counterparts in Scotland and NI can continue to carry out live exports. The NFU has also</p>	<p>Animal welfare is a fully devolved matter and the animal export ban would apply only to England and Wales.</p>

<p><i>animals for fattening and slaughter in England and Wales</i></p>	<p>standards in certain areas: most notably via the banning of the export of live animals for fattening and slaughter.</p> <p>Defra <u>argues that</u> long journeys cause distress and injury, and notes that the UK will be the first country in Europe to enact such a ban, which was not possible under EU rules. Following an earlier consultation, in August 2021 Defra <u>announced</u> it will now work with the farming sector and welfare groups to develop the proposals.</p> <p>As animal welfare is a devolved issue, the animal export ban would apply only to England, as well as Wales which is <u>working closely</u> with HMG on the matter. Northern Ireland will remain aligned to EU animal welfare standards and the government <u>considers the Bill to be a basis for discussion</u> with Scotland.</p>	<p>questioned whether enough consultation has been done to consider the consequences for animal welfare if UK standards are de-harmonised.</p> <p>This could also affect competitiveness vis-à-vis EU farmers. Farming industry bodies have generally also been opposed to the proposed ban <u>on the grounds that</u> that it will damage the industry’s ability to trade with the EU. However, there is limited evidence in the public domain to back this up, bar the NFU’s estimate that retaining more lamb in the UK market could cost the industry £55m over ten years. The NFU <u>recognises</u> that live animal exports have decreased significantly in recent years due to changing practices, but sees them as an “additional marketing option for producers, especially at times of peak supply”.</p> <p>If the precise economic consequences of a potential ban are unclear, animal welfare groups <u>are unanimous</u> in their advocacy of the ban due to the level of animal suffering and fact that some export destinations have lower standards for rearing/slaughtering animals than the UK.</p> <p>An EU Committee on animal transport has discussed the possibility of a similar ban, but there have been no tangible</p>	<p>Legislation is yet to receive final parliamentary approval, although the ban reportedly could be introduced <u>as early as</u> January 2022.</p>
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		<p>developments. The EU is <u>estimated</u> to account for 80% of the world’s live animal exports.</p>	
<p>11. CLIMATE AND ENVIRONMENT</p> <p>PROCEDURAL</p> <p><i>UK establishing Office for Environmental Protection to oversee environmental governance</i></p>	<p>The Environment Bill (currently at 3rd reading in the Lords) aims to transform environmental governance post-Brexit and establish a new Office for Environmental Protection (OEP), which takes on oversight and enforcement functions previously held by EU institutions. The EU Institutions <u>rely</u> on the threat of serious remedies (including fines) as a weapon of last resort in order to ensure compliance.</p> <p>The OEP was set up in interim form -pending the adoption of the Environment Bill - in July 2021, with <u>powers</u> to independently assess the progress of the government’s Environment Plan; enforce environmental protections; and receive complaints about non-compliance with environmental law.</p> <p>The <u>main enforcement actions</u> the OEP can take are ‘information notices’ and ‘decision notices’. The former can be used to demand information from a public authority under investigation for non-compliance. The latter are the next step, setting out the action the OEP thinks should be taken if it detects compliance failures. Unlike the European</p>	<p>A range of expert bodies have expressed concerns about the limited enforcement power of the OEP and the courts, in comparison to their EU equivalent. The Bingham Centre for the Rule of Law <u>says</u> the limited remedies available “undermine the rule of law”, while Greener UK <u>calls the</u> proposed enforcement functions “inadequate” and “unjustified”.</p> <p>A key issue is courts’ <u>limited ability to grant remedies</u>. Courts can in theory take action such as quashing unlawful decisions, but not in cases where such a remedy would cause substantial hardship or prejudice the rights of someone other than the authority; or be detrimental to good administration. Greener UK argues that this puts the interests of “any third party” above those of the environment, even in cases causing serious damage to the natural environment or human health, and advocates greater scope for the Court to carry out a “balancing assessment” of interests.</p> <p>Added to this is the inability of the Courts to stop unlawful actions having legal effect. Where a Court finds that a public</p>	<p>The OEP applies to England and NI only, and its status remains interim until final approval of the Environment Bill in Parliament.</p> <p>Environmental Standards Scotland has been set up but has no statutory powers, pending the adoption of the EU (Scotland) Continuity Act 2021. Should it be approved, its powers will be <u>more wide-reaching</u>, with a</p>

	<p>Commission, the OEP will not have the power to recommend the levying of fines.</p> <p>The final step in the enforcement process is a new legal process called an '<u>environmental review</u>'. If a public authority fails to comply with a decision notice, the OEP can bring legal proceedings against a public authority at the High Court, which in some cases will be able to <u>grant a remedy</u>.</p> <p>The OEP will also be able to apply for a judicial review, which is likely to be a swifter (but still relatively uncertain) route to challenge the actions of a public body. The actions of the OEP could themselves be subject to judicial review.</p> <p>It is important to note that the OEP applies to England and Northern Ireland only, as the policy area is a devolved issue. (See end column for more info on Scottish and Welsh approaches.)</p>	<p>authority has failed to comply with environmental law it must issue a '<u>statement of non-compliance</u>', requiring said authority to issue a statement setting out the steps it intends to take in response. However, it cannot demand any action on behalf of said authority, nor does it stop any unlawful decisions it has taken from having legal effect.</p> <p>Concerns have also been <u>raised</u> over the appointments process for the OEP, whereby the Secretary of State appoints the CEO and board members, and sets its budget. Select Committee recommendations to bring its appointment processes in line with the OBR were rejected by the government. The appointments process, added to the facts that the OEP reports to government and not parliament, and could be abolished by a future government, <u>mean the body may be unwilling to be overtly critical of government</u>, and pose serious questions about the extent of its independence. Professor Colin Reid <u>argues that</u> "no arrangements under domestic law can achieve the degree of independence from the national government that the EU institutions enjoy".</p>	<p>wider set of circumstances in which notices can be issued, and greater to powers to redress cases of non-compliance.</p> <p>Wales set up an Interim Assessor for Environmental Protection in March 2021 for a period of up to two years. The Welsh government accepted an expert group's conclusion of the need for a Commission for Environment in November 2020 but has not since moved to legislate.</p>
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<p>12. CLIMATE AND ENVIRONMENT</p> <p>PASSIVE PROCEDURAL</p> <p><i>EU plans for new chemicals regulation as UK sets up own</i></p>	<p>As a result of Brexit, GB left the EU REACH (Registration, Evaluation, Authorisation and restriction of Chemicals) programme for regulating chemicals. Under the terms of the Protocol, Northern Ireland remains a part of EU REACH. Under EU REACH, substances manufactured in, or imported into, the EEA must be registered with the European Chemicals Agency, submitting information about the chemical and its uses.</p>	<p>Since the end of the transition period, GB has not kept pace with new EU REACH regulations. The EU <u>has legislated</u> (or is in the process of legislating) to restrict 13 more hazardous chemicals, only two of which Defra has announced will be restricted under UK REACH.</p> <p>There is also some concern about the speed of regulation under UK REACH, especially in the early stages. Between 2-6 restrictions are estimated by Defra to come into force each</p>	<p>UK and EU REACH systems diverged as of the end of the Transition Period.</p> <p>UK REACH regulation applies to England, Wales and Scotland, while</p>

<p>regulatory architecture</p>	<p>The UK retained in law EU REACH regulations up to the end of the Transition Period. But subsequent legislation gives government powers to correct ‘deficiencies’ and amend the regulations. This in effect means there is now a distinct ‘UK REACH’ programme.</p> <p>The twin effects of the new UK REACH agenda are 1) that Britain no longer has to follow new EU chemicals regulations and may therefore fall behind, and 2) it can begin to develop its own regulatory regime which could diverge from EU standards.</p>	<p>year in the EU, whereas the regulation of the first two chemicals by UK REACH <u>is expected</u> to take 2.5 years to complete. Added to this, the EU has a plan for a more <u>sustainable chemicals strategy</u>, and there are <u>serious risks</u> that GB will lack the policy levers to keep pace with it, even if it wishes to – despite the Health and Safety Executive recruiting around 60 new staff to work on chemicals regulation. This means regulatory standards are likely to be lower in the UK, especially in the early phases of the UK REACH programme.</p> <p>Should Britain also <u>start to impose new legislation which deviates from EU product standards</u>, companies will have to comply with two distinct sets of standards if operating in the GB and EU markets. The Chemical Industries Association <u>has said</u> that most companies will continue to conform to EU standards as they do not “have the luxury” of conforming to two separate regimes, and EU rules are seen to set the “global bar” and its market is larger. The <u>risk</u> is that some chemicals disappear from the GB market if companies are forced to choose which market to prioritise. For the time being, this should not have a major effect on the GB market, as products which meet EU standards will also meet GB ones.</p>	<p>NI remains a part of EU REACH.</p> <p>EU chemicals strategy for sustainability set to start taking effect in 2022.</p>
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13. FOOD STANDARDS

ACTIVE

UK consultation on whether to reduce level of regulation on gene editing technology in food production

In January 2021 Defra launched a consultation on the possibility of liberalising the regulation around gene editing in England, to allow it to be used in the production of crops and livestock.

Gene editing (GE) is a process through which the genes of an organism are altered (either replaced or removed). Proponents argue this is an acceleration of the same genetic changes which are normally developed through classic breeding methods. It is not the same as genetically modified organisms (GMOs) – whereby genetic material from another species is added. However, following a 2018 ruling, the EU considers gene editing a form of genetic modification. It thus imposes more stringent regulations on GE products (which were retained in UK law post-Brexit), which must be identified, tracked and monitored, and face lengthy risk assessment and approval at member-state level before they can be used. As a result, GE technologies are barely used in the UK or EU.

Defra’s response to its consultation was published in September 2021, with the first step being to allow field trials of gene edited crops in England (provided Defra is notified). Risk assessments and consents will not be required for the trials, which Defra views as “unnecessary regulatory

Gene editing is one of the areas in which England could seek to gain an advantage over the EU in terms of food production and sustainability, and wider environmental goals. It could reduce the use of antibiotics and chemical pesticides, enhance animal welfare, increase the nutritional content of food, and reduce waste, for example by lengthening the shelf life of fruit and vegetables and the development of blight-resistant crops.

A range of scientific experts and industry bodies support the increased use of gene editing, which could be “the most significant policy breakthrough in plant breeding for more than two decades”, given the range of GE technologies developed in the last decade. Some have also, however, expressed concern about the risk of England resultantly lowering its food standards as part of a wider deregulatory agenda, or opening itself up to a range of less-tested GE imports from around the world. TIGRR argues there could be advantages for small businesses which could better compete with major producers if they were able to harness the technology to produce plants with “niche traits”.

A major outstanding question is exactly how GE goods would be regulated differently, if and when the definition of GMOs is amended. Experts have expressed concern about whether

Any policy changes would apply to England only. Defra says it “will work closely with the devolved administrations of Scotland, Wales and Northern Ireland to understand the impacts of future policy changes on their territories.”

	<p>burdens". The next step will then be to bring forward legislation to amend the definition of GMOs to exclude organisms with "genetic changes that could have been achieved through traditional breeding or which could occur naturally." The regulatory changes needed to bring such GE crops onto the market are still being considered.</p> <p>In addition, the recent government-commissioned report by the Taskforce on Innovation, Growth and Regulatory Reform (TIGRR) <u>advocates that</u> government "should actively support research into commercial adoption by UK farmers and growers of gene edited crops, particularly those which help the transition away from agrochemicals to naturally occurring biological resistance."</p>	<p>Defra's definition of 'genetic technologies' is clearly enough defined, and whether a sufficiently wide range of risks (such as <u>unintended effects</u>) have been considered. Until this is clarified, the costs and benefits of any new regime are impossible to determine.</p> <p>Another consideration will be how any proposals for liberalisation align with present and future EU rules. The EU has launched its <u>own inquiry</u> into how it regulates GE goods. Should England opt for much looser regulation than the EU (for instance opting to align with US or <i>lowest common denominator</i> global standards) there is a risk of barriers to trade where English GE goods cannot be exported to the EU.</p> <p>Another issue is that any changes would apply to England only. This risks divergence in food standards between GB and NI, where agri-food checks are already a sensitive issue, as well as political friction within the UK. The Scottish government <u>said</u> it was "disappointed Defra would choose to move unilaterally on this" and that "the Scottish government is committed to keeping closely aligned with the EU". Academics at Scotland's national agricultural college <u>say</u> this will put Scottish farmers at a competitive</p>	
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		disadvantage in the UK market if they do not have access to the same technologies as their English counterparts.	
<p>14. SPS STANDARDS</p> <p>PROCEDURAL</p> <p><i>New checks at border points between EU and GB after GB ceases to follow EU regime for managing human, plant and animal health</i></p>	<p>Under the TCA, GB and the EU have separate regimes for managing human, plant and animal health. To ensure compliance with food and biosecurity regulations, border checks will take place on the import and export of live animals, products of animal origin, and some plants and agri-food products. Key measures include the pre-notification of national authorities before import, completing paperwork such as health certificates, and moving through designated Border Control Post (BCP) which are equipped to handle the goods in question. Checks may be documentary (ensuring the correct paperwork has been completed), identity (the goods are what they say they are) or physical (to ensure compliance with SPS rules).</p> <p>Full SPS checks have been in place for exports from GB to the EU since 1 January 2021, although the exact requirements for exporters have been subject to some change, meaning further adaptation (and thus administrative costs) for businesses. The EU recently <u>elected to delay</u> changes to animal export health certificates (EHCs),</p>	<p>The divergence on SPS standards has led to significant administrative costs and much more friction at the EU-GB border. Moreover, the current reality where there are more checks on exports to the EU than the UK “undermines the competitive position of the UK food and drink industry” <u>according to</u> the Food and Drink Federation. For example, exporters to the EU must provide 24 hours pre-notification, which disrupts supply chains as exporters often do not know their lorry’s license plate details 24 hours in advance, leaving drivers idling until a full 24 hour window is complete.</p> <p>The phasing in of new UK import controls has caused further concerns for businesses. The Food and Drink Federation <u>highlighted</u> uncertainty over processes, a lack of EU veterinarians to inspect consignments, and a lack of the necessary infrastructure in the UK as critical factors. Soon after, the wider introduction of pre-notification requirements and export health certificates were delayed from October 2021 to January and July 2022 respectively.</p> <p>Those concerns aside, the new UK checks are <u>estimated</u> to lead to 270 million pieces of extra paperwork for businesses</p>	<p>The next changes for imports from the EU into GB come into effect in January 2021, with further changes in July 2022.</p> <p>As Northern Ireland remains aligned to EU SPS standards, there are separate checks required for goods moving between GB and NI. The grace periods prior to the introduction of a suite of these were recently extended,</p>

	<p>pushing their introduction back from 21 August 2021 to 15 January 2022.</p> <p>The UK is phasing in checks going the other way <u>more slowly</u>. As of January 2021, imports of high-risk live animal and plant products have to be pre-notified to UK authorities. From January 2022, this requirement will extend to products of animal origin, and high-risk food not of animal origin. From July 2022 most SPS goods will also require export health certificates and must transit through a designated BCP, with an increased rate of physical checks.</p>	<p>each year. The cost of the paperwork has not been quantified but in some cases freight forwarders are charging £70 for an export declaration. There is also <u>concern</u> that some EU businesses have misinterpreted the delay in the introduction of UK border checks as them being waived long-term, and that some are yet to start preparations.</p> <p>At the first meeting of the TCA Partnership Council, the UK government <u>argued</u> that both sides should “deepen cooperation” on SPS and customs, which the EU rejected in absence of UK alignment with EU SPS rules.</p>	<p>apparently indefinitely.</p>
<p>15. ROAD TRANSPORT</p> <p>ACTIVE</p> <p><i>UK relaxes EU rules around number of hours HGV drivers are permitted to drive</i></p>	<p>As an EU member the UK followed the EU Driver Hours Rules for HGV drivers. These stipulate that all hours must be recorded on a tachograph and the driver must not drive for more than: 9 hours per day (this can be raised to 10 hours twice a week), 56 hours in a week or 90 hours in a fortnight. The rules also stipulate that the driver must take a 45-minute break after driving for 4.5 hours, and how breaks can be split up. The rules remained in force in the UK after Brexit because the UK is a signatory to the European Agreement Concerning the Work of Crews of Vehicles Engaged in International Road Transport (AETR) which includes other non-member states such as Russia and Ukraine.</p>	<p>This marks divergence with EU standards, although it could have taken place were UK still an EU member. Indeed, other member states have taken similar measures for other reasons e.g. the Netherlands <u>relaxed</u> driver hours in July 2021 due to adverse weather conditions.</p> <p>However, the grounds for the relaxation of the rules – a shortage of HGV drivers – is likely in part a product of Brexit. Logistics UK <u>says</u> there is a shortfall of around 90,000 drivers. In terms of key causes, it says: “the pandemic halted driver training and testing for over 12 months, while an</p>	<p>The relaxation is currently in place in GB until 31 October 2021 pending further review.</p>

	<p>The government announced a temporary relaxation of how the rules would be applied in GB in July-August 2021 in order to try to mitigate the shortage of haulage drivers in the UK post-Brexit and the adverse impact this, coupled with self-isolation associated with Covid-19, was having on supply chains. This was subsequently <u>extended</u> until 31 October 2021 pending further review.</p> <p>The changes permit the increase in daily driving limits from 9 to 10 hours per week with one of 11 hours allowed up to twice a week or a change in the rest periods to increase the driver hours per driver. The changes do not apply in NI.</p>	<p>estimated 25,000 EU drivers returned home during the pandemic and following the end of the transition period”</p> <p>Wider political tensions could arise if these changes became more permanent and opened a wider discussion about varying the EU working time directive in the UK. This is something HMG has so far stepped away from amending.</p> <p>The Road Hauliers Association and the Unite union have both <u>criticised</u> the government’s decision on the grounds of driver safety and working conditions.</p>	
<p>16. MEDICINES AND MEDICAL DEVICES</p> <p>PASSIVE with a view to becoming ACTIVE</p> <p><i>EU introduces stricter safety regulations on</i></p>	<p>The UK did not implement the EU’s new <u>Medical Device Regulation</u> (EU) – applicable as of May 2021 – and In Vitro Medica Device Regulation – applicable as of May 2022 - which place <u>more stringent requirements</u> on companies to prove medical devices and diagnostic tests are safe, and provide a benefit to patients. Medical devices help diagnose or treat patients, or prevent illness without using drugs (e.g. MRI scanners, hip implants, scalpels, apps to treat depression). The regulation <u>follows a series of scandals</u> caused by malfunctioning breast implants and surgical meshes.</p>	<p>The new EU regulations are causing <u>concern</u> among manufacturers. Many devices presently on the EU market will require recertification through new testing, and in some cases manufacturers are struggling to understand and undertake the necessary testing and documentation. Equally, only around half the Notified Bodies are available to check the new requirements for documentation and testing. This means costs for manufacturers, and potentially longer wait times for new products to enter the EU market (especially as US regulations are presently seen as easier to understand and thus conform to).</p>	<p>The new EU Medical Device Regulation is applicable as of May 2021, and the UK will continue to recognise the EU CE product mark up until 2023.</p> <p>The MHRA launched its</p>

<p>medical devices used in treatment</p>	<p>There is no central EU agency which oversees this regulation, and rather member states authorise public or private organisations – known as ‘Notified Bodies’ - to assess the risks and benefits of products to confirm they meet the necessary regulatory requirements before being put on the market.</p> <p>The UK will continue to recognise the EU’s ‘CE’ mark (which signifies conformity with EU product standards) until 2023. From then on, medical devices must have been approved by UK bodies and given a ‘UKCA’ marking. The regulatory system will sit under the MHRA, and the <u>government says</u> it is designed to “grasp the opportunity of innovation now we have left the EU”. The MHRA delivery plan <u>states</u> that “we will design, consult on and implement a new legislative framework for medical devices.”</p> <p>In September 2021 the MHRA launched a <u>ten-week consultation</u> into how to regulate medical devices across the UK. The Northern Ireland Protocol means that EU medical device regulations continue to apply in NI.</p>	<p>It does not necessarily follow, however, that the UK stands to benefit from more onerous EU regulation. Early drafts of the UK’s own regulatory proposals have <u>reportedly</u> left insiders ‘rattled’. This is not because standards will be higher or lower than the EU’s, but rather because manufacturers will have to comply with a parallel set of standards to access the UK market alongside the EU’s. There are presently no plans for mutual recognition of conformity.</p> <p>The comparatively small size of the UK’s medical devices market vs. the EU’s, combined with the complexity of conforming to a parallel set of UK regulatory standards, means manufacturers are already <u>suggesting</u> they will not bother to undergo the burden of additional testing to meet UK standards. The EU <u>represents</u> 22% of global healthcare spending, whereas the UK represents 3%. The sector is 90% SMEs and thus highly sensitive to additional regulatory costs. The risk is that, from 2023, the UK market loses access to existing technologies, and that innovative technologies take longer to reach the UK market, as manufacturers prioritise access to the US and EU.</p> <p>The greatest business cost in terms of conforming with dual regimes is for more innovative products (e.g. artificial intelligence or novel sensors) and those requiring rigorous</p>	<p>consultation into UK medical device regulation in September 2021.</p>
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		<p>testing on patients: as these often require expensive (millions of pounds), multi-year clinical studies.</p> <p>The UK hopes that it can design a more agile system which – while maintaining the highest international standards – may be able to offer a faster route to market for products than parallel EU processes. The MHRA is currently consulting on such approaches – but given it takes several years to develop and test a medical device it is very unlikely any such innovative framework will be in place by June 2023.</p> <p><u>Another option</u> is to pursue a regulatory system which conforms with standards in other jurisdictions (e.g. Canada, Australia, Singapore). This would, however, give the UK less regulatory autonomy (the reason for divergence from EU standards in the first place) and would be unlikely to be in place in time for 2023. The UK could also automatically allow medical devices which have been approved in other trusted jurisdictions (such as the US and EU) to be used in the UK via a ‘light touch’ registration procedure. But there is unlikely to be mutual recognition, giving a competitive advantage to foreign manufacturers who would enjoy access to the UK market, without UK companies having reciprocal privileges.</p>	
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		<p><u>Recent reporting</u> suggests such a ‘light-touch’ approach may be the MHRA’s preferred option. Yet it also reports that the MHRA is planning budget cuts, despite it needing extra capacity to establish the necessary systems for such a regime.</p>	
<p>17. MEDICINES AND PHARMA</p> <p>PROCEDURAL</p> <p><i>UK ceases to follow certain EU regulations on medicine safety and must introduce own infrastructure for assessments</i></p>	<p>Under the EU’s Falsified Medicines Directive (FMD), medicines in the EU have a ‘Unique Identifier’ as a guard against falsification. Since 1 January 2021 GB <u>has been disconnected</u> from the FMD’s safety system, meaning it is no longer possible to verify and authenticate medicines using the EU’s Unique Identifier system. Packs with FMD safety features are still accepted in GB, but there are <u>no obligations</u> to apply additional GB-specific safety features.</p> <p>Northern Ireland remains covered by the FMD under the terms of the NI Protocol. This means medicines produced in GB no longer meet all of the EU standards necessary to be placed on the market in NI. Consequently, medicines sent from GB to NI will have to obtain additional certification and undergo testing (both carried out in NI) as part of new <u>import controls</u>. However, there has been no immediate impact due to a <u>12-month phase-in period</u>, which in September 2021 appeared to be <u>extended indefinitely</u>.</p>	<p>The divergent standards between GB and NI mean generic medicines manufacturers will have to carry out <u>duplicate</u> licensing, production and distribution systems for GB and NI markets respectively, once the grace period expires. There is a major risk that many GB-based manufacturers will simply not meet the new procedural demands required for exports to NI, due to the additional costs. This could lead to a shortage of certain GB-produced medicines in NI (hence the delaying of the grace period in September 2021). GB is the source of the majority of NI’s medicines and the British Generic Manufacturers Association <u>warned</u> in July that its companies had put over 2,000 medicines on notice for withdrawal from NI. Some manufacturers in the UK had <u>already started to withdraw medicines from NI</u> because they cannot meet the regulatory costs.</p> <p>The EU <u>acknowledges</u> that “the new situation is still particularly challenging” and proposes that the new checks</p>	<p>New checks on medicines entering NI from GB have seemingly been extended indefinitely. The MHRA is yet to publish proposals on any new plans medicines authorisation.</p>

		<p>and approvals for exports to NI could be done in GB (addressing the cost for suppliers of moving regulatory procedures into NI), if it is ensured that the goods are not distributed beyond NI into the EU. However the UK <u>rejects</u> the proposals as still complex to operate, and not addressing the fact that certain medicines such as new cancer drugs would still need approval in NI. It instead has <u>suggested</u> that the simplest way forward would be to remove medicines from the NI Protocol entirely, calling the new rules “<u>unviable</u>”. This underlines that, alongside the risk of shortages in NI, the medicines issue could accentuate the wider political acrimony around the viability of the NI Protocol, given how far apart the UK and EU’s proposed solutions remain.</p> <p>Added to this, a much greater burden of verification work now falls on the MHRA, which can no longer collaborate with bodies from 27 EU member states in its verification processes. Yet <u>the FT reports</u> that the MHRA has outlined plans to make 25% of its staff redundant amid budget cuts. There has been little information from the MHRA on a) how it is going to respond to the increased demand for verification work or b) whether it will introduce new, bespoke verification checks on medicines in the UK. The risk</p>	
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		is that UK systems for verifying the safety of medicines thus become less robust.	
<p>18. FINANCIAL SERVICES</p> <p>ACTIVE</p> <p><i>UK announces plans for new strategic approach to fintech</i></p>	<p>The Independent Strategic Review of UK Fintech by Ron Kalifa (The Kalifa Review) was published on 26 February 2021. It aims to maintain and develop the UK’s competitiveness in fintech by calling for a regulatory strategy and wide-ranging policy framework for fintech. It makes 17 recommendations in five areas (policy and regulation; skills and talent; investment; international attractiveness and competitiveness; and national connectivity).</p> <p>One of the most significant recommendations is to build on the innovative regulatory sandboxes created by the Financial Conduct Authority (FCA) which have been reproduced internationally (sandboxes also form part of the BEIS consultation in response to the TIGRR report), and to create a digital scalebox, which would provide fintech and regtech firms additional support with the aim of fostering growth in small firms and in “priority fintech areas” as set out by the government.</p>	<p>The new regulatory framework proposed by the Kalifa Review follows the EU’s Digital Finance and Retail Payments package launched in September 2020. The UK’s Review goes further by including cross-sectoral issues such as skills which apply to all areas of the economy. Whilst this is a difference in approach, it is not a regulatory issue. It is a matter of interpretation as to whether this is an instance of divergence that would prohibit further equivalence determinations from the EU.</p> <p>The Chancellor announced the government’s plans for beginning to implement the Kalifa recommendations in April 2021. This forms part of the Treasury’s wider identification of digital finance as a key potential area of post-Brexit growth. He announced that the FCA will lead on the creation of a scale box and committed to create an industry-led Centre for Finance, Innovation and Technology to lead the implementation of the recommendations. A scale-up visa was announced in the 2021 Budget which allows skilled workers with a job offer at a recognised ‘scale-up’ company</p>	<p>Recommendations from the review are now being taken forward but there are not yet dates for formal implementation.</p> <p>Financial services are neither a part of the NI Protocol, nor a devolved competency, meaning changes will apply to the UK as a whole.</p>

		to qualify for a fast-track visa without the need for sponsorship.	
<p>19. FINANCIAL SERVICES</p> <p>ACTIVE</p> <p><i>UK conducting review into EU Solvency II legislation, with a view to tailoring to UK needs</i></p>	<p>The EU Directive Solvency II came into effect in January 2016. It set out the regulatory requirements for insurance firms including their financial resources, risk assessment and management, disclosure and reporting requirements and their governance and accountability. It has been widely identified in analysis of post-Brexit financial services regulation as an area where divergence from the EU could lower the regulatory requirements on firms whilst not posing additional risks for customers or financial stability. A <u>review</u> by HM Treasury of Solvency II was launched in October 2020.</p> <p>Two main areas have been identified for potential change. First is the risk margin. This is the potential cost of transferring the insurance risks to another part should an insurer fail. It was not included in UK regulation prior to the introduction of Solvency II and it is seen as not well suited to a low interest rate environment meaning that the industry <u>argues</u> that insurers hold billions of excess capital that could be used to increase investment elsewhere.</p>	<p>The EU is also <u>conducting</u> a review of Solvency II, reflecting wider concerns about its risk margin.</p> <p>The UK industry sees opportunities to increase its competitiveness through setting a risk margin tailored to the UK market, thereby diverging from the EU. However, the Bank of England’s Prudential Regulation Authority has expressed concerns regarding the amount of additional investment such changes may bring about, revealing tensions between maintaining market stability and considering international competitiveness as now required in regulatory changes in the UK.</p>	<p>Further information gathering is ongoing and policy decisions have not been made to date.</p>

	<p>The second area is the matching ratio. This is in place to ensure that long term investments used to pay long term liabilities such as annuities are valued on a similarly long-term basis. However, the industry argues that this is too restrictive and c.£60bn of funds could be reinvested in areas such as green growth if the matching adjustment was changed to allow more investment in different types of investment.</p>		
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